

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

MICHAEL and KELLY YURCIC,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	Case No. 02-CV-3737
	:	
PURDUE PHARMA, L.P., PURDUE	:	
PHARMA, INC., PURDUE FREDERICK	:	
COMPANY, ABBOTT LABORATORIES,	:	JURY TRIAL DEMANDED
ABBOTT LABORATORIES, INC.,	:	
MORTON RUBIN, M.D., and HOWARD	:	
R. CORBIN, M.D.,	:	
	:	
Defendants.	:	
	:	

**ANSWER AND AFFIRMATIVE DEFENSES
OF THE PURDUE FREDERICK COMPANY**

COMES NOW defendant The Purdue Frederick Company ("PF"), by counsel, and in Answer to plaintiffs' Complaint herein, states as follows:

1. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 1 of the Complaint, except admits that the Complaint avers that plaintiffs Michael and Kelly Yurcic ("Plaintiffs") are citizens of the Commonwealth of Pennsylvania residing at an address in Harrisburg, Pennsylvania.

2. PF denies each and every allegation contained in paragraph 2 of the Complaint, except admits that Purdue Pharma L.P. is a Delaware limited partnership with its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut.

3. PF denies each and every allegation contained in paragraph 3 of the Complaint, except admits that Purdue Pharma L.P. was, at relevant times, engaged in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling or distributing OxyContin® Tablets ("OxyContin") throughout the United States, including in the Commonwealth of Pennsylvania.

4. PF denies each and every allegation contained in paragraph 4 of the Complaint, except admits that Purdue Pharma Inc. is a New York corporation with its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut.

5. PF denies each and every allegation contained in paragraph 5 of the Complaint.

6. PF denies each and every allegation contained in paragraph 6 of the Complaint, except admits that Purdue Pharma Inc. is the general partner of Purdue Pharma L.P.

7. PF denies each and every allegation contained in paragraph 7 of the Complaint, except admits that it is a New York corporation with its principal place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut.

8. PF denies each and every allegation contained in paragraph 8 of the Complaint, except admits that it was, at relevant times, engaged in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling or distributing OxyContin throughout the United States, including in the Commonwealth of Pennsylvania.

9. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 9 of the Complaint.

10. PF denies each and every allegation contained in paragraph 10 of the Complaint, except admits that Abbott Laboratories has provided limited and defined promotional assistance in the marketing of OxyContin in Pennsylvania and elsewhere in the United States.

11. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 11 of the Complaint.

12. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 12 of the Complaint.

13. PF denies each and every allegation contained in paragraph 13 of the Complaint, except admits that Abbott Laboratories Inc. has provided limited and defined promotional assistance in the marketing of OxyContin in Pennsylvania and elsewhere in the United States.

14. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 14 of the Complaint.

15. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 15 of the Complaint.

16. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 16 of the Complaint.

17. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 17 of the Complaint.

18. PF admits the allegations contained in paragraph 18 of the Complaint.

19. PF denies each and every allegation contained in paragraph 19 of the Complaint, except admits that OxyContin is an opioid analgesic prescription medication with an abuse liability similar to morphine as described in the professional prescribing information approved by the Food and Drug Administration of the United States Department of Health and Human services ("FDA") that accompanies each package of OxyContin ("package insert"), which package insert speaks for itself as to its content.

20. PF denies each and every allegation contained in paragraph 20 of the Complaint, except admits that Purdue Pharma L.P. developed and/or along with certain of the other defendants owns patents covering OxyContin, which was approved for sale by the FDA in December 1995, and states that the patent documents with respect to OxyContin speak for themselves as to their content.

21. PF denies each and every allegation contained in paragraph 21 of the Complaint, except admits that OxyContin was available initially in 10 mg., 20 mg. and 40 mg. tablets, and that the tablet strengths describe the amount of oxycodone per tablet.

22. PF admits the allegations contained in paragraph 22 of the Complaint.

23. PF denies each and every allegation contained in paragraph 23 of the Complaint, except admits that in May 2001 shipments of OxyContin 160 mg. tablets were suspended.

24. PF denies each and every allegation contained in paragraph 24 of the Complaint, except admits that Purdue Pharma L.P. and Abbott Laboratories entered into a co-promotion agreement and further admits that Abbott Laboratories and Abbott Laboratories, Inc. have provided limited and defined promotional assistance in the marketing of OxyContin in the United States.

25. PF denies each and every allegation contained in paragraph 25 of the Complaint, except admits that OxyContin is designed to provide controlled delivery of oxycodone over twelve hours and that many shorter-acting medications must be taken more frequently but states that the oxycodone in OxyContin is released over time.

26. PF denies each and every allegation contained in paragraph 26 of the Complaint, except admits some strengths of OxyContin contain more oxycodone than many immediate-release formulations but states that the oxycodone in OxyContin is released over time.

27. In response to the allegations contained in paragraph 27 of the Complaint, PF admits that OxyContin is a federally controlled Schedule II drug and refers to the applicable federal statutes and regulations for the definitions and characteristics of Schedule II drugs.

28. In response to the allegations contained in paragraph 28 of the Complaint, PF admits that OxyContin is a federally controlled Schedule II drug and refers to the applicable federal statutes and regulations for the definitions and characteristics of Schedule II drugs.

29. PF denies each and every allegation contained in paragraph 29 of the Complaint, except admits that OxyContin was approved for sale by the FDA in December 1995

and that factory sales of OxyContin in the United States in the year 2000 approximated one billion dollars.

30. PF denies each and every allegation contained in paragraph 30 of the Complaint.

31. PF denies each and every allegation contained in paragraph 31 of the Complaint, except admits that Purdue Pharma L.P. received a letter dated May 11, 2000 from the FDA, which letter speaks for itself as to its content. PF states that although Purdue Pharma L.P. denied the FDA reviewer's opinion that the advertisement referenced in paragraph 31 was false or misleading, Purdue Pharma L.P. voluntarily cancelled further publication of such advertisement.

32. PF denies each and every allegation contained in paragraph 32 of the Complaint.

33. PF denies each and every allegation contained in paragraph 33 of the Complaint, except states that risks from the use of OxyContin are well known to medical providers and are described in the package insert that accompanies each package of OxyContin, which package insert speaks for itself as to its content.

34. PF denies each and every allegation contained in paragraph 34 of the Complaint and, with respect to the allegation that OxyContin has an "addictive nature," states that risks from the use of OxyContin are well known to medical providers and are described in the package insert that accompanies each package of OxyContin, which package insert speaks for itself as to its content.

35. PF denies each and every allegation contained in paragraph 35 of the Complaint, except states that certain of the defendants conducted studies on OxyContin, and that the results of those studies speak for themselves as to their source and content.

36. PF denies each and every allegation contained in paragraph 36 of the Complaint, except states that certain of the defendants conducted studies on OxyContin, and that the results of those studies speak for themselves as to their source and content.

37. PF denies each and every allegation contained in paragraph 37 of the Complaint.

38. PF denies each and every allegation contained in paragraph 38 of the Complaint, except admits that OxyIR was introduced in December 1996.

39. PF denies each and every allegation contained in paragraph 39 of the Complaint.

40. PF denies each and every allegation contained in paragraph 40 of the Complaint.

41. PF denies each and every allegation contained in paragraph 41 of the Complaint.

42. PF denies each and every allegation contained in paragraph 42 of the Complaint, except states that Purdue Pharma L.P. has sponsored numerous seminars on pain management in various locations to educate health care professionals on proper pain

management, and evaluated and selected professionals from the attendees for the purpose of teaching and training others in appropriate pain management.

43. PF denies each and every allegation contained in paragraph 43 of the Complaint.

44. PF denies each and every allegation contained in paragraph 44 of the Complaint, except admits that Purdue Pharma L.P. maintains an internet site at "www.partnersagainstpain.com," which, as to its content, has spoken for and speaks for itself.

45. PF denies each and every allegation contained in paragraph 45 of the Complaint, except admits that OxyContin has become a widely used product for the treatment of moderate to severe pain in Pennsylvania and throughout the country. PF denies that the acceptance of OxyContin for this purpose by the medical community has been as a result of "aggressive marketing tactics." Rather, OxyContin has become accepted by the medical community for the relief of moderate to severe pain because it has been found to be safe and effective for that purpose.

46. PF denies each and every allegation contained in paragraph 46 of the Complaint.

47. PF denies each and every allegation contained in paragraph 47 of the Complaint.

48. PF denies each and every allegation contained in paragraph 48 of the Complaint, except states that efforts are ongoing to develop an oxycodone formulation so as to reduce the potential for abuse by persons taking or using OxyContin contrary to the instructions

for its proper use. PF further states that the FDA requires rigorous proof of the safety and efficacy of such reformulation for its intended use, including extensive clinical trials in human subjects, before approving a New Drug Application for the reformulated product.

49. PF denies each and every allegation contained in paragraph 49 of the Complaint, except admits that OxyContin, like any prescription medication, can be abused by a person taking or using it contrary to the instructions for proper use.

50. PF denies each and every allegation contained in paragraph 50 of the Complaint, except states that efforts are ongoing to develop an oxycodone formulation so as to reduce the potential for abuse by persons taking or using OxyContin contrary to the instructions for its proper use. PF further states that the FDA requires rigorous proof of the safety and efficacy of such reformulation for its intended use, including extensive clinical trials in human subjects, before approving a New Drug Application for the reformulated product.

51. PF denies each and every allegation contained in paragraph 51 of the Complaint.

52. PF denies each and every allegation contained in the first sentence of paragraph 52 of the Complaint. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in the second sentence of paragraph 52.

53. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 53 of the Complaint.

54. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 54 of the Complaint.

55. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 55 of the Complaint.

56. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 56 of the Complaint.

57. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 57 of the Complaint.

58. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 58 of the Complaint.

59. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 59 of the Complaint.

60. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 60 of the Complaint.

61. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 61 of the Complaint.

62. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 62 of the Complaint.

63. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 63 of the Complaint.

64. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 64 of the Complaint.

65. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 65 of the Complaint.

66. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 66 of the Complaint.

67. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 67 of the Complaint.

68. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 68 of the Complaint.

69. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 69 of the Complaint.

70. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 70 of the Complaint.

71. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 71 of the Complaint.

72. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 72 of the Complaint.

73. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 73 of the Complaint.

74. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 74 of the Complaint.

75. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 75 of the Complaint.

76. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 76 of the Complaint.

77. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 77 of the Complaint.

78. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 78 of the Complaint.

79. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 79 of the Complaint, except denies that any of the alleged symptoms and injuries described in paragraph 79 were "from OxyContin use."

80. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 80 of the Complaint.

81. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 81 of the Complaint.

82. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 82 of the Complaint.

83. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 83 of the Complaint, except denies that any

portion of the advice plaintiff Michael Yurcic allegedly received as described in paragraph 83 was "[a]s a direct result of ingesting OxyContin."

84. PF denies each and every allegation contained in paragraph 84 of the Complaint.

85. PF denies each and every allegation contained in paragraph 85 of the Complaint.

86. PF denies each and every allegation contained in paragraph 86 of the Complaint.

87. PF denies each and every allegation contained in paragraph 87 of the Complaint.

88. PF denies each and every allegation contained in paragraph 88 of the Complaint.

89. PF denies each and every allegation contained in paragraph 89 of the Complaint.

90. PF denies each and every allegation contained in paragraph 90 of the Complaint.

AS TO COUNT I

91. PF repeats and realleges its responses to the allegations contained in paragraphs 1 through 90 of the Complaint as if fully set forth herein.

92. PF denies each and every allegation contained in paragraph 92 of the Complaint, except states that to the extent it owed a duty to any person(s), it exercised reasonable care in the performance of such duty.

93. PF denies each and every allegation contained in paragraph 93 of the Complaint, except states that risks from the use of OxyContin are well known to medical providers and are described in the package insert which accompanies each package of OxyContin, which package insert speaks for itself as to its content.

94. PF denies each and every allegation contained in paragraph 94 of the Complaint.

95. PF denies each and every allegation contained in paragraph 95 of the Complaint.

96. PF denies each and every allegation contained in paragraph 96 of the Complaint, except admits that certain of the defendants were and are engaged in the business of manufacturing, marketing, promoting, distributing or selling OxyContin.

97. PF denies each and every allegation contained in paragraph 97 of the Complaint.

98. PF denies each and every allegation contained in paragraph 98 of the Complaint.

99. PF denies each and every allegation contained in paragraph 99 of the Complaint, except states that risks from the use of OxyContin are well known to medical

providers and are described in the package insert which accompanies each package of OxyContin, which package insert speaks for itself as to its content.

100. PF denies each and every allegation contained in paragraph 100 of the Complaint.

101. PF denies each and every allegation contained in paragraph 101 of the Complaint.

102. PF denies each and every allegation contained in paragraph 102 of the Complaint.

In response to the "WHEREFORE" clause following paragraph 102 of the Complaint, PF denies that plaintiffs are entitled to the relief claimed or to any relief whatsoever.

AS TO COUNT II

103. PF repeats and realleges its responses to the allegations contained in paragraphs 1 through 102 of the Complaint as if fully set forth herein.

104. PF denies each and every allegation contained in paragraph 104 of the Complaint.

105. PF denies each and every allegation contained in paragraph 105 of the Complaint.

106. PF denies each and every allegation contained in paragraph 106 of the Complaint.

107. PF denies each and every allegation contained in paragraph 107 of the Complaint.

108. PF denies each and every allegation contained in paragraph 108 of the Complaint.

109. PF denies each and every allegation contained in paragraph 109 of the Complaint.

110. PF denies each and every allegation contained in paragraph 110 of the Complaint.

111. PF denies each and every allegation contained in paragraph 111 of the Complaint, except states that risks from the use of OxyContin are well known to medical providers and are described in the package insert which accompanies each package of OxyContin, which package insert speaks for itself as to its content.

112. PF denies each and every allegation contained in paragraph 112 of the Complaint.

113. PF denies each and every allegation contained in paragraph 113 of the Complaint.

114. PF denies each and every allegation contained in paragraph 114 of the Complaint.

In response to the "WHEREFORE" clause following paragraph 114 of the Complaint, PF denies that plaintiffs are entitled to the relief claimed or to any relief whatsoever.

AS TO COUNT III

115. PF repeats and realleges its responses to the allegations contained in paragraphs 1 through 114 of the Complaint as if fully set forth herein.

116. PF denies each and every allegation contained in paragraph 116 of the Complaint, except states that to the extent it owed a duty to any person(s), it exercised reasonable care in the performance of such duty.

117. PF denies each and every allegation contained in paragraph 117 of the Complaint.

118. PF denies each and every allegation contained in paragraph 118 of the Complaint.

119. PF denies each and every allegation contained in paragraph 119 of the Complaint.

120. PF denies each and every allegation contained in paragraph 120 of the Complaint.

121. PF denies each and every allegation contained in paragraph 121 of the Complaint, except states that risks from the use of OxyContin are well known to medical providers and are described in the package insert which accompanies each package of OxyContin, which package insert speaks for itself as to its content.

122. PF denies each and every allegation contained in paragraph 122 of the Complaint.

123. PF denies each and every allegation contained in paragraph 123 of the Complaint.

124. PF denies each and every allegation contained in paragraph 124 of the Complaint.

In response to the "WHEREFORE" clause following paragraph 124 of the Complaint, PF denies that plaintiffs are entitled to the relief claimed or to any relief whatsoever.

AS TO COUNT IV

125. PF repeats and realleges its responses to the allegations contained in paragraphs 1 through 124 of the Complaint as if fully set forth herein.

126. PF states that no response by it is required to paragraph 126 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 126.

127. PF states that no response by it is required to paragraph 127 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 127.

128. PF states that no response by it is required to paragraph 128 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 128.

129. PF states that no response by it is required to paragraph 129 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 129.

130. PF states that no response by it is required to paragraph 130 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 130.

131. PF states that no response by it is required to paragraph 131 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 131, except denies that plaintiff Michael Yurcic suffered injury as a result of an alleged "OxyContin addiction."

132. PF states that no response by it is required to paragraph 132 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 132.

133. PF states that no response by it is required to paragraph 133 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 133.

134. PF states that no response by it is required to paragraph 134 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 134.

135. PF states that no response by it is required to paragraph 135 of the Complaint, as Count IV of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, and because plaintiffs' use of the term "Defendant's" in paragraph 135 makes it unclear as to which defendant plaintiffs refer, PF denies each and every allegation contained in paragraph 135.

PF need not respond to the "WHEREFORE" clause that follows paragraph 135 of the Complaint because Count IV is expressly directed to a defendant other than PF. To the extent that a response by PF is required, however, PF denies that plaintiffs are entitled to the relief claimed or any relief whatsoever.

AS TO COUNT V

136. PF repeats and realleges its responses to the allegations contained in paragraphs 1 through 135 of the Complaint as if fully set forth herein.

137. PF states that no response by it is required to paragraph 137 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 137.

138. PF states that no response by it is required to paragraph 138 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To

the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 138.

139. PF states that no response by it is required to paragraph 139 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 139.

140. PF states that no response by it is required to paragraph 140 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 140.

141. PF states that no response by it is required to paragraph 141 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 141.

142. PF states that no response by it is required to paragraph 142 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 142, except denies that plaintiff Michael Yurcic suffered injury as a result of an alleged "OxyContin addiction."

143. PF states that no response by it is required to paragraph 143 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To

the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 143.

144. PF states that no response by it is required to paragraph 144 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 144.

145. PF states that no response by it is required to paragraph 145 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 145.

146. PF states that no response by it is required to paragraph 146 of the Complaint, as Count V of the Complaint is expressly directed to a defendant other than PF. To the extent a response by PF is required, however, and because plaintiffs' use of the term "Defendant's" in paragraph 146 makes it unclear as to which defendant plaintiffs refer, PF denies each and every allegation contained in paragraph 146.

PF need not respond to the "WHEREFORE" clause that follows paragraph 146 of the Complaint because Count V is expressly directed to a defendant other than PF. To the extent that a response by PF is required, however, PF denies that plaintiffs are entitled to the relief claimed or any relief whatsoever.

AS TO COUNT VI

147. PF repeats and realleges its responses to the allegations contained in paragraphs 1 through 146 of the Complaint as if fully set forth herein.

148. PF denies knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 148 of the Complaint.

149. PF denies each and every allegation contained in paragraph 149 of the Complaint.

150. PF denies each and every allegation contained in paragraph 150 of the Complaint.

151. PF denies each and every allegation contained in paragraph 151 of the Complaint.

152. PF denies each and every allegation contained in paragraph 152 of the Complaint, except states that risks from the use of OxyContin are well known to medical providers and are described in the package insert which accompanies each package of OxyContin, which package insert speaks for itself as to its content.

153. PF denies each and every allegation contained in paragraph 153 of the Complaint.

154. PF denies each and every allegation contained in paragraph 154 of the Complaint.

155. PF denies each and every allegation contained in paragraph 155 of the Complaint.

In response to the "WHEREFORE" clause following paragraph 155 of the Complaint, PF denies that plaintiffs are entitled to the relief claimed or to any relief whatsoever.

PF denies each and every allegation in the Complaint not heretofore specifically admitted.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state any claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claimed injuries and damages were caused, in whole or in part, by the actions or omissions of others for whose conduct PF is not responsible. For example, irresponsible reports appearing in the media have suggested to the public methods of diverting, abusing, misusing, and otherwise improperly or illegally using OxyContin.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent that the proximate cause of any alleged injury was plaintiff Michael Yurcic's choice to use, misuse, or abuse OxyContin in a manner other than that recommended. The intervening or superseding cause of any injury allegedly sustained by the plaintiff accordingly would be plaintiff Michael Yurcic's own conduct.

FOURTH AFFIRMATIVE DEFENSE

The intervening or superseding cause of any injury allegedly sustained by the plaintiffs may have been conduct which is illicit, criminal, or otherwise improper, and for which conduct PF cannot be held responsible.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, waiver, estoppel and unclean hands.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of assumption of risk.

SEVENTH AFFIRMATIVE DEFENSE

PF has complied with all requirements promulgated by and under the FDA, the Drug Enforcement Administration, and all other governing federal agencies and statutes. The product at issue, OxyContin, was approved pursuant to the applicable statutes and regulations. The labeling for OxyContin was also approved by the FDA, and the marketing was conducted in conformity with all applicable federal regulations. Such actions and federal regulations and statutes preempt plaintiffs' claims under state law.

EIGHTH AFFIRMATIVE DEFENSE

The doctrine of primary jurisdiction bars the claims of plaintiffs. The FDA has primary jurisdiction over the issues raised in the Complaint. The FDA, pursuant to federal law, has exclusive regulatory control of products such as that at issue here. Therefore, this Court should defer any consideration of the issues raised in the Complaint which are properly within the purview of the FDA and refer such issues to that agency for determination.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by the applicable statutes of limitation.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the contributory and comparative negligence of plaintiffs.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' recovery must be barred, in whole or in part, to the extent that the plaintiffs failed to mitigate the alleged injuries or damages.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent that plaintiff Michael Yurcic consented to the acts alleged in the Complaint.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred to the extent that those claims are based on an alleged duty to warn of risks associated with the use of OxyContin, inasmuch as plaintiff Michael Yurcic was warned or was otherwise made aware of alleged dangers of the product, and further, any such alleged dangers were not beyond that which would have been contemplated by the ordinary consumer of the product with the ordinary knowledge common to the community.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the design, manufacture, inspection, packaging, and/or labeling of OxyContin are, and have always been, consistent with the generally recognized technological, medical, scientific, and industrial state-of-the-art.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because statements, promotions, and advertisements of OxyContin are protected by the First Amendment to the United States Constitution and the correlative provisions of the Pennsylvania Constitution.

SIXTEENTH AFFIRMATIVE DEFENSE

While denying any and all allegations of negligence, wrongdoing, fault, or liability, PF states that it would be entitled to a full credit, offset, *pro-rata* reduction, or

percentage reduction, based on the percentage of fault attributable to each settling defendant, in the event plaintiffs settle with any defendant, pursuant to the applicable statutes.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from recovering any damages by virtue of the fact that the dangers, if any, claimed by plaintiffs were open and obvious.

EIGHTEENTH AFFIRMATIVE DEFENSE

If the product allegedly involved in this action was defective or unreasonably dangerous, which PF denies, plaintiff Michael Yurcic was aware thereof and unreasonably proceeded to make use of the product in that condition.

NINETEENTH AFFIRMATIVE DEFENSE

PF states that all OxyContin lawfully sold or distributed in the United States carries warnings which adequately informed plaintiff Michael Yurcic of any alleged health risks of using OxyContin.

TWENTIETH AFFIRMATIVE DEFENSE

PF states that plaintiff did not justifiably rely on activities attributed by plaintiff to PF in the Complaint, and that any injuries or damages complained of in the Complaint were not caused by PF's alleged actions.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred to the extent the injuries alleged in the Complaint resulted from a preexisting and/or unrelated medical or psychiatric condition and/or idiosyncratic reaction to OxyContin and not from any act or omission by any of the defendants or by any defect in OxyContin. PF further states that the damages and injuries alleged, if any, may have

been caused or enhanced by a preexisting medical or psychiatric condition of plaintiff Michael Yurcic that was not related to the distribution, sale or use of OxyContin.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claimed damages are too speculative to form the basis for relief.

TWENTY-THIRD AFFIRMATIVE DEFENSE

While denying that plaintiffs suffered any injury for which PF is liable, PF avers that any injuries suffered by plaintiff have been mitigated, in whole or in part, by reimbursement from collateral sources.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the intervention of a learned intermediary or intermediaries whose acts, omissions, or fault, if any, are the proximate cause of plaintiffs' injuries, damages, or losses, if any.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from recovering any damages by virtue of the fact that any harm caused by OxyContin was caused by an inherent aspect of the product which could not be eliminated without compromising its usefulness.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by the plaintiffs without substantially impairing the usefulness or intended purpose of the product.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims violate the due process provisions of the United States Constitution and the correlative provisions of the Pennsylvania Constitution to the extent that they seek to deprive PF of the procedural and substantive safeguards, including traditional defenses to liability.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for punitive damages violate the Excessive Fines and Penalties clause of the United States Constitution and the correlative provisions of the Pennsylvania Constitution. Such claims also violate PF's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and by the correlative provisions of the Pennsylvania Constitution.

TWENTY-NINTH AFFIRMATIVE DEFENSE

To the extent that the laws of other jurisdictions apply, PF invokes each and every constitutional defense available to it under the constitutions (or similar charters) of each of the other forty-nine states, the District of Columbia, the Commonwealth of Puerto Rico, and the territories and possessions of the United States. This specifically includes, but is not limited to, provisions relating to due process, access to the courts, freedom of speech, freedom of association, freedom to petition the government for redress of grievances, and limitations on compensatory and punitive damages.

THIRTIETH AFFIRMATIVE DEFENSE

To the extent that the laws of other jurisdictions apply, PF invokes each and every statutory and common law defense available to it under the laws of each of the other forty-nine states, the District of Columbia, the Commonwealth of Puerto Rico, and the territories and

possessions of the United States with respect to each of the claims alleged in the Complaint that is recognized in that jurisdiction.

THIRTY-FIRST AFFIRMATIVE DEFENSE

PF adopts and incorporates by reference any affirmative defense asserted by any other defendant to this action, to the extent such affirmative defense applies to PF.

THIRTY-SECOND AFFIRMATIVE DEFENSE

The Complaint has been filed in an improper venue.

PF reserves the right to assert, and hereby gives notice that it intends to rely upon, any other defense that may become available or appear during discovery proceedings or otherwise in this case and hereby reserves the right to amend its answer to assert any such defense.

WHEREFORE, PF respectfully requests that the Court dismiss the Complaint in its entirety with prejudice and award PF its costs and disbursements, including attorneys' fees, incurred in defending this action together with such other relief as the Court deems just and proper.

Dated: June 13, 2002

AKIN, GUMP, STRAUSS, HAUER &
FELD, L.L.P.

By _____
Edward F. Mannino (Atty. I.D. #04504)
David L. Comerford (Atty. I.D. #65969)
Katherine Menapace (Atty. I.D. #80395)
Jason Snyderman (Atty. I.D. #80239)
One Commerce Square
2005 Market Street, Suite 2200
Philadelphia, Pennsylvania 19103
(215) 965-1200

Attorneys for Defendant
The Purdue Frederick Company

JURY DEMAND

COMES NOW defendant The Purdue Frederick Company and demands trial by jury.

Edward F. Mannino

CERTIFICATE OF SERVICE

I, Jason A. Snyderman, Esquire, hereby certify that a copy of the foregoing Answer and Affirmative Defenses of Purdue Frederick Company was mailed to the following by ordinary U.S. mail, postage prepaid, this 13th day of June, 2002:

Sol H. Weiss, Esquire
Marc Stolee, Esquire
Anapol, Schwartz, Weiss, Cohan,
Feldman & Smalley, P.C.
1900 Delancey Place
Philadelphia, PA 19103

Joseph E. O'Neil, Esquire
Lavin, Coleman, O'Neil, Ricci
Finarelli & Gray
510 Walnut Street, Suite 1000
Philadelphia, PA 19106

Allan H. Starr, Esquire
White & Williams, LLP
1800 One Liberty Place
Philadelphia, PA 19103

Angelo L. Scaricamazza, Jr., Esquire
Kenneth Fair, Esquire
Naulty, Scaricamazza & McDevitt
Suite 1600 John F. Kennedy Blvd.
Philadelphia, PA 19103

Jason A. Snyderman